



**Department of Veterans Affairs
Office of Inspector General**

Office of Healthcare Inspections

Report No. 13-04520-201

Healthcare Inspection

**Potential Exposure to
Creutzfeldt-Jakob Disease
VA Connecticut Healthcare System
West Haven, Connecticut**

July 1, 2014

Washington, DC 20420

To Report Suspected Wrongdoing in VA Programs and Operations:

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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections conducted an oversight review regarding potential exposure of two patients to Creutzfeldt-Jakob Disease (CJD) at the VA Connecticut Healthcare System (facility), West Haven, CT. We reviewed the facility's procedures for reprocessing of neurosurgical instruments, handling and tracking of loaner instrument trays, and responding to the potential exposure and the follow-up actions taken post-exposure. In addition, we reviewed Veterans Health Administration (VHA) reprocessing requirements for neurosurgical instruments.

We concluded that the facility took appropriate steps to address potential patient exposure to CJD. Managers were proactive in seeking counsel from subject matter experts within the VA and other Government agencies to ensure that proper patient follow-up and notification occurred in a timely manner. Facility providers notified and met with the involved patients and/or their family members to discuss the potential exposure to CJD, the risks of CJD transmission, and answer questions or concerns. Providers documented clinical disclosures in the patients' electronic health records.

Although the facility met the recommended manufacturer's minimum requirement of 4 minutes for sterilization of surgical instruments, the facility amended its process by increasing sterilization time from 4 to 18 minutes for neurosurgical instruments. Additionally, managers implemented a process for tracking all loaner instruments from receipt to return. We concluded that VHA had appropriate policies and procedures for reprocessing neurosurgical instruments. We made no recommendations.

The Veterans Integrated Service Network and Facility Directors concurred with the report. (See Appendixes A and B, pages 9–10, for the Directors' comments.) No further action is required.



JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an evaluation of the VA Connecticut Healthcare System's (facility) management of two veteran patients who had been potentially exposed to Creutzfeldt–Jakob disease (CJD). The specific objectives were to review the facility's procedures for reprocessing neurosurgical instruments, handling and tracking loaner instrument trays, and responding to the potential exposure and the follow-up actions taken post-exposure. In addition, we reviewed Veterans Health Administration (VHA) reprocessing requirements for neurosurgical instruments.

Background

The facility, part of Veterans Integrated Service Network (VISN) 1, comprises two campuses located in West Haven and Newington, CT. The West Haven campus has 230 beds and provides patient care services that include internal medicine, surgery, psychiatry, physical medicine and rehabilitation, neurology, oncology, dentistry, and geriatrics and extended care. Newington is an ambulatory care center that provides primary and specialty care.

In August 2013, media reports described the potential exposure of patients to CJD. The source patient, who was located in New Hampshire, had died and during autopsy was diagnosed with suspected CJD. The instruments used on the source patient were also used on 15 other patients—8 in a New Hampshire community hospital, 5 in a Massachusetts community hospital, and 2 at the facility.

CJD Overview

CJD is a rare, degenerative, invariably fatal brain disorder, with about 200 cases per year in the United States. It usually appears later in life and runs a rapid course, with symptoms occurring at about age 60. There are three main categories of the disease:

- Sporadic: Person has no known risk factors. This accounts for at least 85 percent of cases.
- Hereditary: Person has a family history of the disease and/or tests positive for a genetic mutation associated with CJD. About 5–10 percent of CJD cases in the United States are hereditary.
- Iatrogenic: Disease is transmitted by exposure to brain or nervous system tissue, usually through certain medical procedures.¹

¹ Rutala W, Weber D. SHEA Guideline for Disinfection and Sterilization of Prion-Contaminated Medical Instruments. *Inf Control Hosp Epidemiol* 2010;25:107–117.

Healthcare-associated² CJD infections have occurred in less than 1 percent of all cases. All known cases of healthcare-associated or iatrogenic CJD resulted from exposure to infectious brain, pituitary, or eye tissue.^{3,4}

CJD Exposure Overview at the Facility

Due to the complexities and costs of the instruments, hospitals often use loaner surgical instruments from a vendor or another hospital in order to provide necessary instruments to perform scheduled procedures without the financial burden of purchasing them.⁵ A neurosurgical loaner instrument tray was delivered to the facility in early May 2013 and was used during surgery involving two facility patients. The instruments were reprocessed following the manufacturer's recommended decontamination and sterilization instructions before and after each case.

The first patient (Patient A), an 85-year-old male, had a brain biopsy to determine the reason for his brain lesions. The second patient (Patient B), a 67-year-old male, underwent a craniotomy⁶ for resection of a brain tumor. Table 1 below describes the dates and types of surgeries.

Table 1. Dates and Types of Surgeries

Patient	Date of Surgery	Diagnosis	Surgical Procedure
Patient A	May 30, 2013	Right homonymous hemianopsia (absence of vision toward one side of the visual world)	Left parietooccipital stereotactic brain biopsy
Patient B	June 11, 2013	Meningioma (brain tumor that develops from the meninges—the membrane that surrounds the brain and spinal cord)	Craniotomy for resection meningioma

Source: *OIG Review of Electronic Health Records*

In late August, the neurosurgical instrument manufacturer (Medtronic, Inc.) notified the facility that the three instruments included in the loaner tray, a Vertek II Articulating Arm,

² Healthcare-associated infections are ones patients acquire while receiving healthcare treatment for other conditions.

³ Brown P. Environmental causes of human spongiform encephalopathy. In: Baker H, Ridley RM, eds. *Methods in Molecular Medicine: Prion Diseases*. Totowa, NJ: Humana Press; 1996:139–154.

⁴ Brown P, Gibbs CJ, Rodgers-Johnson P, et al. Human spongiform encephalopathy: the National Institutes of Health series of 300 cases of experimentally transmitted disease. *Ann Neurol* 1994;35:513–529.

⁵ Seavy R. Reducing the Risks Associated with Loaner Instrumentation and Implants. *AORN Journal*, 2010;92:3:322.

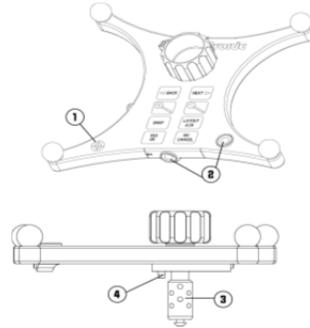
⁶ Surgical removal of part of the skull to expose the brain. It is the most commonly performed surgery for brain tumor removal.

a Passive Planar Probe, and a Small Passive Cranial Reference Frame, had been used on the source patient in a non-VA facility in May. The source patient had died and was suspected of having CJD. The diagnosis of CJD was later confirmed by the Centers for Disease Control and Prevention (CDC). Exhibit 1 shows the instruments in the loaner tray.

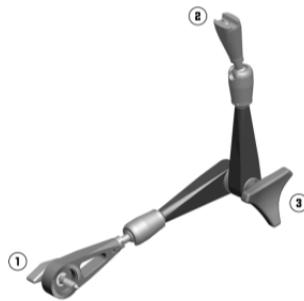
Exhibit 1. Instruments Included in the Loaner Tray



Passive Planar Probe



Small Passive Cranial Frame



Vertek II Articulating Arm

Source: Manufacturer's website

Two of the three loaner instruments had no contact with the facility patients' brain tissue. The Passive Planar Probe, used to locate the specific surgical area, was the only instrument inserted into the facility patients' brain tissue.

Decontamination and Sterilization Parameters

In 1999, the World Health Organization (WHO) recommended the use of sodium hypochlorite (chlorine bleach) or sodium hydroxide (NaOH) to disinfect and/or sterilize instruments if instruments could not be destroyed or quarantined after use on a possible CJD patient.⁷ However, FDA investigators found that: (1) autoclaving (sterilizing) in a 1 Normal (N) solution of NaOH causes darkening of some instruments; (2) soaking in 1N NaOH at room temperature damages carbon steel but not stainless steel or titanium; and (3) soaking in chlorine bleach corrodes gold-plated instruments and will damage

⁷ World Health Organization. WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies, March 1999.

some stainless steel instruments.⁸ In addition, the CDC indicated that staff should avoid gaseous exposure to NaOH. Since the release of the WHO guidelines, studies have demonstrated the efficacy of using enzymatic detergents followed by steam sterilization in eliminating prions⁹ from steel surfaces.^{10,11} Table 2 describes the recommended procedures for the disinfection and sterilization of surgical instruments potentially contaminated with CJD from several organizations.

Table 2. Recommended Disinfection and Sterilization Procedures for Potentially Contaminated CJD Instruments

Source	Cleaning	Disinfection	Sterilization
1. The Society for Healthcare Epidemiology of America (SHEA)	Routine cleaning and disinfection: Initial manual cleaning, soaking in enzymatic solutions, washing in washer/sterilizer		<p>Four options (in order of effectiveness):</p> <ol style="list-style-type: none"> 1. 273°F for 18 minutes (prevacuum sterilizer¹²); 2. 270°F for 1 hour (gravity displacement sterilizer¹³); 3. Immerse in 1N sodium hydroxide for 1 hour, rinse in water, transfer to open pan and sterilize at 250°F (gravity displacement) or 273°F (prevacuum) for 1 hour; OR 4. Immerse instruments in 1N NaOH for 1 hour and sterilize (gravity displacement) at 250°F for 30 minutes.
2. The American National Standards Institute/ Association for the Advancement of Medical Instrumentation	<p>Routine cleaning:</p> <p>Initial manual cleaning, soaking in enzymatic solutions, washing in washer/sterilizer</p>	<p>Alternative:</p> <p>1. Soak instruments in a solution such as saline or water to reduce the adherence of tissue or blood to the instruments</p>	Rinse, clean, wrap and sterilize using conventional means

⁸ Brown S, Merritt K, Woods T, Busick D. Effects on Instruments of the World Health Organization – Recommended Protocols for Decontamination after Possible Exposure to Transmissible Spongiform Encephalopathy-Contaminated Tissue. *J Biomed Mater Res Part B Appl Biomater*. 2005;72(1):186–90.

⁹ An abnormal form of a normal protein (due to the absence of a nucleic acid), which is resistant to heat and disinfecting agents inactivation and can be transmitted person-to-person. It is thought to be the infectious agent that causes CJD and other neurodegenerative diseases.

¹⁰ Lawson V. Enzymatic detergent Treatment Protocol that Reduces Protease-resistant Prion Protein Load and Infectivity from Surgical Steel Monofilaments Contaminated with a Human-derived Prion Strain. *J Gen Virol* Oct. 2007; 88 (10): 2905–2914.

¹¹ Rutala W, Weber D. SHEA Guideline for Disinfection and Sterilization of Prion-Contaminated Medical Instruments. *Inf Control Hosp Epidemiol* 2010;25:107–117.

¹² A sterilizer where steam is introduced at the top or the sides; air is removed before the steam is introduced to allow for more immediate steam penetration into the items.

¹³ A sterilizer where steam is introduced at the top or the sides, and air is forced out of the bottom of the sterilizer.

Source	Cleaning	Disinfection	Sterilization
(ANSI/AAMI)		2. Devices can be initially decontaminated by steam sterilization at 273°F for ≥18 minutes in a prevacuum sterilizer, 250–270°F in a gravity displacement sterilizer OR 3. Soak instruments in a 1N solution of NaOH for 1 hour	
3. The International Association of Healthcare Central Service Materiel Management (IAHCSMM)	No specific guidance	No specific guidance	1. 275–278°F for 18 minutes (prevacuum) 2. 270°F for 1 hour (gravity displacement) or 250°F for 1 ½ hours (gravity displacement)

Source: OHI

In this instance, the facility followed the manufacturer’s instructions for the loaner instruments and its own reprocessing procedures for surgical instruments that were consistent with industry standards cited in Table 2.

Scope and Methodology

We gathered information from key facility staff members. We interviewed a CJD subject matter expert from a VA facility and the prion epidemiologist from the CDC. We discussed the potential exposure in New Hampshire and Massachusetts with the respective State Health Departments. We also interviewed a VHA reusable medical equipment reprocessing subject matter expert.

We reviewed the patients’ electronic health records (EHRs), the facility’s reprocessing procedures, relevant facility policies and procedures, pertinent medical literature, and the manufacturer’s information on the involved instruments.

We conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

Inspection Results

Issue 1: Reprocessing of Neurosurgery Instruments

We found no evidence that sterilization procedures were compromised. The probe manufacturer recommended a sterilization time of 4–18 minutes, and the facility used a 4-minute sterilization time. After consultation with CDC, the Connecticut State Department of Health, and local infectious disease specialists, the facility determined that its sterilization processes were within established guidelines, including the minimum recommended sterilization time. Facility managers told us that experts determined that actual risk of CJD exposure to patients was minimal. We determined that the loaner neurosurgery instruments were decontaminated and sterilized according to the facility's standard operating procedure (SOP) and manufacturer's instructions.

The facility's surgical instrument SOP includes pre-soaking the instruments in the operating room after every surgical procedure with an enzymatic product. Once the instruments are delivered to the Sterile Processing Service, staff manually clean them with enzymatic cleaners to flush instruments or equipment with lumens,¹⁴ items are again cleaned in an ultrasonic cleaner, and they are placed in a washer/sterilizer. The instruments are then dried and packaged for steam sterilization at 275 degrees (°) Fahrenheit (F) for 4 minutes. After the potential CJD exposure incidents, and to further minimize the risk of CJD transmission, the facility adopted a longer sterilization time of 18 minutes for neurosurgical instruments by incorporating industry standards^{15,16} and recommendations from SHEA.¹⁷

Issue 2: Handling and Tracking of Loaner Instruments

The facility utilized a standard process for handling loaner instruments and appropriately decontaminated and sterilized the loaner instruments upon receipt and after each patient use according to the manufacturer's instructions.

However, at the time of the delivery of the loaner tray in May 2013, the facility did not have a process in place for tracking¹⁸ loaner instruments. The facility published a policy in May 2013, which was later revised in January 2014. The initial tracking tool used for signing in loaner instruments was initiated in early June 2013; however, the final tool did not come into use until mid-September. The facility did not have tracking records for the loaner instruments for the two patients.

¹⁴ An inner open space/cavity or the bore of a tube.

¹⁵ International Association of Healthcare Central Service Materiel Management *Central Service Technical Manual*, 7th edition, pp 324–325.

¹⁶ ANSI/AAMI St 79:2010&A1:2010&A2:2011, p. 163–167.

¹⁷ Rutala W, Weber D. SHEA Guideline for Disinfection and Sterilization of Prion-Contaminated Medical Instruments. *Inf Control Hosp Epidemiol* 2010;25:107–117.

¹⁸ Process for documenting loaner instrument information from the time of delivery or upon receipt until the final disposition when the instrument is returned to the manufacturer.

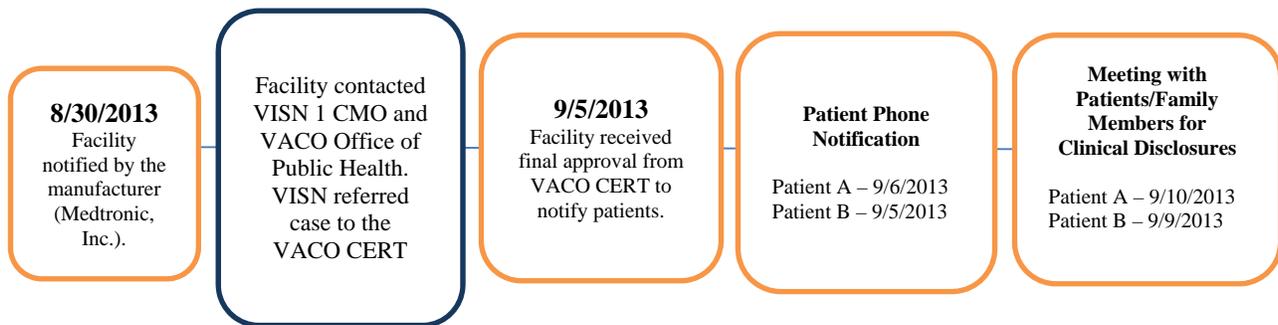
Issue 3: Facility Response and Follow-Up Actions

We found that the facility initiated multiple actions in response to the potential exposure. These included a multidisciplinary review of the internal events; ongoing communication by the facility's epidemiologist with key staff at the New Hampshire, Connecticut, and Massachusetts Departments of Public Health, the prion epidemiologist at the CDC, and the manufacturer representative; revision of policies; and staff training. Additionally, the facility Chief Nurse and Epidemiologist provided information to staff and answered questions.

Facility clinicians notified both patients and/or their family members, and providers conducted clinical disclosures¹⁹ according to VHA policy.²⁰ Once notified by the manufacturer on August 30 of the possible exposure, facility managers contacted the VA Central Office (VACO) Office of Public Health and VISN 1 Chief Medical Officer (CMO). The VISN then referred the issue to the VACO Clinical Event Response Team (CERT) for review and guidance. On September 5, the facility received approval to notify the patients. Both patients were notified by phone within 24 hours.

The hematology-oncology physician briefly discussed the potential exposure with Patient A's wife by telephone on September 6. The decision was made to have additional discussions on September 10 during the patient's clinic visit. During that clinic visit, the provider decided to admit the patient to the hospital for dehydration and falls. We did not find documentation of disclosure to the patient during that visit; however, an addendum progress note was written on October 1, documenting that the patient and his family were provided with an information sheet regarding his CJD-exposure during his September 10 clinic visit. Face-to-face clinical disclosure for Patient B was conducted on September 9. Exhibit 2 below shows the timeline of the patient notification process.

Exhibit 2. Patient Notification Timeline



Source: OHI

¹⁹ A process by which the patient's clinician informs the patient or the patient's personal representative, as part of routine clinical care, that a harmful or potentially harmful adverse event has occurred during the course of care.

²⁰ VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, October 2, 2012.

Issue 4: VHA Requirements for Reprocessing of Neurosurgical Instruments

We queried a VHA subject matter expert to determine whether appropriate procedures are in place for disinfection and sterilization of neurosurgical instruments. We determined that VHA utilizes appropriate policies and procedures for reprocessing of neurosurgical instruments that are consistent with acceptable published guidelines from the following organizations:

- International Association of Healthcare Central Service Materiel Management – Central Service Technical Manual, 7th edition
- ANSI/AAMI St 79:2010&A1:2010&A2:2011
- SHEA Guideline for Disinfection and Sterilization of Prion-Contaminated Medical Instruments

Conclusions

We concluded that the facility took appropriate steps to address potential patient exposure to CJD. Managers were proactive in seeking counsel from subject matter experts within the VA and other Government agencies to ensure that proper patient follow-up and notification occurred in a timely manner. Facility providers notified and met with the involved patients and/or their family members to discuss the potential exposure to CJD, the risks of CJD transmission, and answer questions or concerns. Providers documented clinical disclosures in the patients' EHRs.

Although the facility met the recommended manufacturer's minimum requirement for sterilization of surgical instruments, the facility amended its process by increasing sterilization time from 4 to 18 minutes for neurosurgical instruments. Additionally, managers implemented a process for tracking all loaner instruments from receipt to return. We concluded that VHA had appropriate policies and procedures for reprocessing neurosurgical instruments. We made no recommendations.

VISN Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: June 11, 2014

From: Director, VA New England Healthcare System (10N1)

Subject: Healthcare Inspection—Potential Exposure to Creutzfeldt-Jakob Disease, VA Connecticut Healthcare System, West Haven, CT

To: Director, Region Office of Healthcare Inspections (54LA)
Director, Management Review Service (VHA 10AR MRS OIG Hotline)

I have reviewed and concur with the action plans regarding Potential Exposure to Creutzfeldt-Jakob Disease at VA Connecticut HCS, West Haven, CT.

Sincerely,



Michael F. Mayo-Smith, MD, MPH
Network Director

Facility Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: June 10, 2014

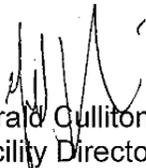
From: VA Connecticut Healthcare System Director (689/00)

Subject: Healthcare Inspection—Potential Exposure to Creutzfeldt-Jakob Disease, VA Connecticut Healthcare System, West Haven, CT

To: Director, VA New England Healthcare System (10N1)

I have reviewed and concur with the action plans regarding Potential Exposure to Creutzfeldt-Jakob Disease at VA Connecticut HCS, West Haven, CT.

Sincerely,



Gerald Culliton
Facility Director

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the OIG at (202) 461-4720.
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